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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/381,344	09/20/99	SEEMANN	2481.1640

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EXAMINER
SHUKLA, R

ART UNIT	PAPER NUMBER
1632	3

DATE MAILED: 02/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/381,344

Applicant(s)

SEEMANN ET AL.

Examiner

Ram Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

1. The examiner prosecuting this case has changed. Please refer your inquiries to the Patent Analyst listed at the end of the action or to Examiner Shukla, new examiner assigned to prosecute this case.
2. Applicants' telephonic conversation with Ms. Karen Hauda, SPE that all the claims were not included in the restriction contained in the office action mailed 12-19-00 is acknowledged. Accordingly, the restriction requirement set forth in the previous office action of 12-19-00 has been vacated and a new restriction is required.
3. Claims 1-15 are pending in the instant application.

Election/Restrictions

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- species of R¹, R², R³ and X, recited in claims 1 and 2.
- species of pharmaceutical compounds recited in claim 3
- diseases listed in claim 7.

5. Claims 1-15 are directed to a method for increasing the tolerance of a mammal to transgenic cells, after discontinuing concomitant immunosuppressant therapy, by administering a pharmaceutical or pharmaceutical combination comprising p15-deoxyspergualin, anti-T-cell antibody, corticosteroid, azathioprine, methotrexate or a compound of the formula (I) or (II) or an optionally stereoisomeric form of the compound of the formula I or II and/or a physiologically tolerable salt of the compound of the formula I wherein:

Applicant is required to select one of the following species with respect to claims 1-15:

p15-deoxyspergualin, anti-T-cell antibody, corticosteroid, azathioprine, methotrexate or a compound of the formula (I) or a compound of the formula (II) or an optionally stereoisomeric form of the compound of the formula I or an optionally stereoisomeric form of the compound of the formula II, a physiologically tolerable salt of the compound of the formula I ;

and

one of the following species for each of R¹, R², R³ and X:

- species of R¹ :
- a) (C₁-C₄)-alkyl
 - b) (C₃-C₅)-cycloalkyl

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- species of R^2 :
- c) (C_2-C_6) -alkenyl or
 - d) (C_2-C_6) -alkynyl
 - a) $-CF_3$
 - b) $-O-CF_3$
 - c) $-S-CF_3$
 - d) $-OH$
 - e) $-NO_2$
 - f) halogen
 - g) benzyl
 - h) phenyl
 - i) $-O$ -phenyl
 - k) $-CN$ or
 - l) $-O$ -phenyl, mono- or polysubstituted by
 - 1) (C_1-C_4) -alkyl
 - 2) halogen
 - 3) $-O-CF_3$ or
 - 4) $-O-CH_3$
- species of R^3 :
- a) (C_1-C_4) -alkyl
 - b) halogen or
 - c) a hydrogen atom and
- species of X :
- a) $-CH$ group or
 - b) a nitrogen atom

6. Claim 2 and 3 are directed to the method as claimed in claim 1, wherein the pharmaceutical comprises the compound of the formula I and/or II or an optionally stereoisomeric form of the compound of the formula I or II and/or a salt of the compound of the formula I wherein:

Applicant is required to select one of the following species with respect to claims 2 and 3:

one of the following species for each R^1 , R^2 , R^3 and X .

- species of R^1 :
- a) methyl
 - b) cyclopropyl or
 - c) (C_3-C_5) -alkynyl

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species of R²: -CF₃ or -CN,
species of R³: a hydrogen atom or methyl, and
species of X: a -CH group.

7. Applicant is required to select one of the following species with respect to claim 3: pharmaceutical comprises N-(4-trifluoromethylphenyl)-5-mehtylisoxazole-4-carboxamide, N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide, 2-cyano-3-cyclopropyl-3-hydroxy acrylic acid (4-cyanophenyl)amide or N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxyhept-2-en-6-ynecarboxamide.

8. Applicant is required to select one of the following species with respect to claims 7, 14 and 15:

hereditary disorders such as cystic fibrosis, familial hypercholesterolemia, hemophilia, sickle cell anemia; of nerve and brain disorders such as Parkinson's, Alzheimer's or Kreuzfeld-Jakob syndrome; of rheumatic disorders, osteoarthritis, osteoporosis or arthrosis, of phenylketonuria; of metabolic disorders; of inflammations; of carcinomatous disorders; of infectious disorders; or of hormone and growth disorders.

9. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP ' 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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9. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species of pharmaceuticals and the chemical side chains recited in claim 1-3 lack common significant structure. Likewise the disease conditions recited in claim 7 also lack a common special technical feature, structure and function.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703) 305-6608. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Kay Pinkney whose telephone number is (703) 305-3553.

Ram R. Shukla, Ph.D.


KAREN M. HAUDA
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